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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,611	05/04/2001	Andy Swenson	10265.96.1	9485

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,611	SWENSON ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 11-43* is/are pending in the application.

4a) Of the above claim(s) *16-20 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,11-15 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination, Request for Extension of Time, and Amendment filed 01/06/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/06/05 has been entered.

Election/Restrictions

During a telephone conversation with Robyn N. Phillips on 08/20/02 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-15, and 21-38. Claims 16-20, and 39-43 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 8, 11-13, 21-23 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. US 6,120,803.

Wong discloses a prolonged release dosage form comprising active agent, and mixture of water-soluble polymer and hydroattractant (see abstract; column 8, lines 54-56; and claim 1). Water-soluble polymer includes maltodextrin in an amount of about 5-90% by weight; and hydroattractant includes cellulose fiber in an amount of about 5-60% by weight (columns 10-11; claims 3, 4 and 7). The percent amounts of maltodextrin and cellulose fiber if calculated in weight ratio would fall within the claimed range. Wong also discloses the dosage form provides sustained release of active agent over a prolonged period of time, for example from about 4 hours up to about 20-24

hours (column 4, lines 64-66; column 15, lines 29-60; column 21, lines 42-46; and column 22, lines 1-10). Wong further discloses the dosage form is a tablet dosage form (column 16, lines 46-59).

Wong does not expressly teach the degree of polymerization as recited in claims 12 and 13. However, it is the position of the examiner that such limitation is clearly inherent because Wong discloses the use of the same cellulose powder being disclosed in the specification at page 9, paragraph 022, Elcema® (see Wong at column 10, line 67, and example 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, 11, 21, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al. US 6,069,172.

Bertini teaches a pharmaceutical preparation for oral administration comprising ketoprofen (see abstract). The preparation in the form of controlled release, slow-release, or immediate release comprises from 10-80% of lactose, microcrystalline cellulose, powder cellulose, starch and various maltodextrins, and their mixtures (column 10, lines 1-48).

Bertini does not teach the weight ratio between the maltodextrin and the cellulose powder. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable weight ratio between maltodextrin and cellulose powder to obtain the claimed invention, because Bertini teaches the use of both, maltodextrin and cellulose powder in a slow release formulation (column 10, lines 33-49).

Claims 21-23 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Baichwal et al. US 5,128,143.

Bertini is relied upon for the reason stated above. Bertini does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify the

pharmaceutical preparation of Bertini in view of the teaching of Baichwal, because the cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can be blended with a wide variety of active medicaments for sustained/controlled release oral dosage form.

Claims 2-6, 33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Lord et al. US 6,417,227.

Bertini is relied upon for the reasons stated above. Bertini teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonyl methane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the excipient in view of the teaching of Bertini, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 1-6, 8, 11-13, 21-33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. US 6,120,803, in view of Lord et al. US 6,417,227.

Wong is relied upon for the reasons stated above. Wong teaches the use of a variety of active agents, but is silent as to the teaching of the specific active agents being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonyl methane (columns 2-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the dosage form of Wong using the active agent taught by Lord, because Wong teaches the use of combination of active agents (column 20, lines 35-60), because Wong teaches the dosage form suitable for active agents that are poorly absorbed in the lower gastrointestinal tract, but well absorbed in the small intestine (column 19, lines 10-13), and because Wong teaches the use of anti-inflammatory active agent (column 18, lines 7-9).

It is noted that Wong does not explicitly teach that the dosage form is suitable for reducing stomach irritation. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re*

Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, it would have been obvious to one of ordinary skill in the art to modify the teachings of Wong with the expectation of at least similar result, because Wong teaches a sustained release dosage form using a gel-forming polymer, wherein the polymer swells upon contact with fluid (column 7, lines 16-24), and because Wong teaches the use of nonirritating dosage form to obtain an efficacy and safety formulation.

Claims 14, 15 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., in view of Lord et al. and Grain processing Corporation.

Wong and Lord are relied upon for the reason stated above. Wong is silent as to the teaching of the claimed maltodextrin.

Grain processing corporation teaches maltodextrin, such as Maltrin® having no protein, fat, or fiber, which is commonly used in consumer products as dry mixes (pages 1-2). Thus, it would have been obvious for one of ordinary skill in this art to use the maltodextrin in view of the teaching of Grain processing Corporation to obtain the claimed invention, because Grain processing Corporation teaches Maltrin® is safe for patients, easily digestible, and water-soluble (see page 1).

Response to Arguments

Applicant's arguments filed 01/06/05 have been fully considered but they are not persuasive.

Applicant argues that Bertini does not teach the weight ratio between powdered cellulose and maltodextrin. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable weight ratio between maltodextrin and cellulose powder to obtain the claimed invention, because Bertini teaches the use of both, maltodextrin and cellulose powder in a slow release formulation (column 10, lines 33-49).

Applicant argues that Bertini does not teach or disclose the combination of cellulose and maltodextrin. Contrary to the applicant's argument, applicant's attention is called to the phrase "their mixture" intended for the use of excipients including powdered cellulose and maltodextrin at column 10, lines 41-43.

Applicant argues that neither Baichwal or Lord teach or suggest the use of the claimed sustained release compositions as recited in the claims, because both, Baichwal and Lord teach the use of water-soluble "film-forming polymer" in stead of "powdered cellulose". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Baichwal or Lord is relied upon solely for the teaching of the release time or for the active agent.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takeo et al., Bhutani, Kumar, Kolter et al., Berner et al., and Obae et al. are cited as of interest for the teachings of powdered cellulose.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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